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| EXAMINER | |
|---|---|
| DEAK, LESLIE R | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3761 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/706,300 | TU ET AL. | |
| | Examiner | Art Unit | |
| | LESLIE R. DEAK | 3761 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6 and 46-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 46-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, and 46-49, 54, 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 5,980,928 to Terry.

In the specification and figures, Lynch discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 2, 4, 5, 46, 47, 54, 57, Lynch discloses an implant 100 with a body comprised of a biocompatible material. wherein the implant comprises an outlet end or distal portion sized and shaped to reside in a physiological outflow pathway such as Schlemm's canal, and an inlet end or proximal portion sized and shaped to reside in the anterior chamber of the eye, wherein the device permits fluid communication from the anterior chamber to Schlemm's canal (see column 6, lines 50-64, column 9, lines 49-67).

With regard to applicant's recitation of the body comprising a therapeutic drug, Lynch discloses in the provisional application that, in an embodiment, the apparatus may comprise a reservoir containing a drug or therapeutic agent deliverable to adjacent tissues, but does not disclose that the implant itself comprises a therapeutic agent. However, Terry discloses an ocular implant for the treatment of conjunctivitis wherein the implant comprises a time release matrix of antibiotics (which corresponds to

applicant's claim drawn to a coating) that elute to the surrounding tissue when implanted in the eye (see column 2, lines 1-10, column 3, lines 36-61). The implant disclosed by Terry allows for long-term, low-dose treatment (see column 2, lines 41-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent, as disclosed by Terry, to the glaucoma implant disclosed by Lynch in order to provide a long-term, low dose pharmaceutical treatment for an ocular condition, as taught by Terry.

With regard to claims 48 and 49, Lynch discloses a method of introducing an implant into the claimed location to facilitate drainage. Lynch fails to specifically disclose the particular drainage method in conjunction with therapeutic drug delivery, but does disclose the drainage and drug delivery as separate procedures. However, Terry discloses an ocular implant for the treatment of conjunctivitis wherein the implant comprises a time release matrix of antibiotics (which corresponds to applicant's claim drawn to a coating) that elute to the surrounding tissue when implanted in the eye (see column 2, lines 1-10, column 3, lines 36-61). The implant disclosed by Terry allows for long-term, low-dose treatment (see column 2, lines 41-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent, as disclosed by Terry, to the glaucoma implant in the method disclosed by Lynch in order to provide a long-term, low dose pharmaceutical treatment for an ocular condition, as taught by Terry.

3. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 5,980,928 to Terry , further in view of US 7,033,603 to Nelson.

In the specification and figures, the cited prior art discloses the device substantially as claimed by applicant (see rejection above) with the exception of the particular drugs or materials used as bioactive agents in the device. Nelson discloses an implantable hydrogel device that provides drug delivery to various internal locations within a patient. The device disclosed by Nelson may include a growth factor, a gene, TGF-beta, and heparin (see column 7, lines 60-67, column 8, lines 1-22, column 18, lines 50-67, column 17, lines 36-41). It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant suggested by the cited prior art with the therapeutic agents disclosed by Nelson in order to provide the desired therapeutic treatment to the patient.

4. Claims 4, 5 (as an alternative to the rejection presented above), 48 and 49 (as an alternative to the rejection presented above), 50, 51, 53, 56, 58-60, 63-65 67-72are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,521,210 to Wong in view of US 5,980,928 to Terry.

In the specification and figures, Wong discloses the method substantially as claimed by applicant. With regard to claims 48, 49, 50, 51, 58, 59, 63-65, Wong discloses a method for treating an ocular disorder such as glaucoma, comprising the steps of forming an incision in the sclera of the eye, (see column 5, lines 10-15), inserting an implant 40 through the incision into the anterior chamber 32, advancing the implant across a section of the anterior chamber 32 until it comes to rest on stop arm 44 (see column 5, lines 35-47), and allowing the implant to drain aqueous humor from the anterior chamber towards the choroid, which comprises a physiological outflow pathway (see column 5, lines 1-3, 45-53, FIG 4). Wong discloses that the implant disclosed by Wong is positioned to allow fluid to enter the choroidal space while the posterior end 46 of the implant 40 contacts the choroid 22 (see FIG 4).

Wong fails to disclose that the method uses an implant that comprises a therapeutic drug. However, Terry discloses an ocular implant for the treatment of conjunctivitis wherein the implant comprises a time release matrix of antibiotics (which corresponds to applicant's claim drawn to a coating, and which may comprise more than one antibiotic) that elute to the surrounding tissue when implanted in the eye (see column 2, lines 1-10, column 3, lines 36-61). The implant disclosed by Terry allows for long-term, low-dose treatment (see column 2, lines 41-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent, as disclosed by Terry, to the glaucoma implant in the method disclosed by Wong in order to provide a long-term, low dose pharmaceutical treatment for an ocular condition, as taught by Terry.

With regard to claim 53, the implant illustrated by Wong comprises two opposing L shapes, meeting the limitations of the claim.

With regard to claim 56, the implant disclosed by Wong comprises arms or protrusions 44 that are used to stabilize the implant within the eye tissue (see FIG 13).

With regard to claims 60, 67-72, Wong discloses that the implant comprises channels and holes 94 that direct or control fluid movement from the anterior chamber to the choroid wherein arms 44 extend away from the channels or lumens (see column 6, lines 42-48). Wong discloses a method for treating an ocular disorder such as glaucoma, comprising the steps of forming an incision in the sclera of the eye, (see column 5, lines 10-15), inserting an implant 40 through the incision into the anterior chamber 32, advancing the implant across a section of the anterior chamber 32 until it comes to rest on stop arm 44 (see column 5, lines 35-47), and allowing the implant to drain aqueous humor from the anterior chamber towards the choroid, which comprises a physiological outflow pathway (see column 5, lines 1-3, 45-53, FIG 4).

5. Claims 1, 2, 4, 5, 46 (as an alternative to the rejections above), 52, and 54, 57, (as an alternative to the rejection above) are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 2005/01197371 A1 to Bene.

In the specification and figures, Lynch discloses the apparatus substantially as claimed by applicant. With regard to claims 1, 2, 4, 5, 46, 47, 54, 57, Lynch discloses an implant 100 with a body comprised of a biocompatible material. wherein the implant

comprises an outlet end or distal portion sized and shaped to reside in a physiological outflow pathway such as Schlemm's canal, and an inlet end or proximal portion sized and shaped to reside in the anterior chamber of the eye, wherein the device permits fluid communication from the anterior chamber to Schlemm's canal (see column 6, lines 50-64, column 9, lines 49-67).

With regard to applicant's recitation of the body comprising a therapeutic drug, Lynch discloses in the provisional application that, in an embodiment, the apparatus may comprise a reservoir containing a drug or therapeutic agent deliverable to adjacent tissues, but does not disclose that the implant itself comprises a therapeutic agent. However, Bene discloses an ocular implant that may be coated, impregnanted, or surround a therapeutic drug for delivery to the adjacent eye tissue (see at least paragraphs 0059-0061). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent as disclosed by Bene to the implant disclosed by Lynch in order to distribute therapeutic agents to eye tissue, as taught be Bene.

With regard to claims 52 and 55, Bene discloses that the shunt body 311 may comprise a lumen (see FIG 30), while the outside of the shunt may comprise an outer layer or covering with a therapeutic substance, which corresponds to a second portion of the shunt, appended to the first portion (see paragraph 0061).

6. Claims 61, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,521,210 to Wong in view of US 5,980,928 to Terry, further in view of US 2005/01197371 A1 to Bene.

In the specification and figures, the cited prior art discloses the method substantially as claimed by applicant (see rejection above).

With regard to claim 61 and the recitation that the implant comprises a hollow filled with therapeutic drug, Bene discloses an ocular implant that may comprise a hydrogel that surrounds a therapeutic drug for controlled diffusion of the drug to the adjacent eye tissue (see at least paragraphs 0059-0061). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a therapeutic agent enclosed in a hydrogel as disclosed by Bene to the implant suggested by the cited prior art in order to distribute therapeutic agents to eye tissue at a controlled rate, as taught be Bene.

With regard to claims 62 and 66, Bene discloses that the shunt body 311 may comprise a lumen (see FIG 30), while the outside of the shunt may comprise an outer layer or covering with a therapeutic substance, which corresponds to a second portion of the shunt, appended to the first portion (see paragraph 0061).

***Response to Arguments***

7. Applicant's amendment and arguments filed 1 May 2008 have been entered and considered.

8. Applicant's arguments with respect to the 102(e) rejection over Lynch based on the disclosures in the provisional application are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lynch and Terry.

9. Applicant's arguments with respect to the 103(a) rejections of the claims over the combination of White and Bene are persuasive. However, upon further consideration, a new ground(s) of rejection is made in view of Lynch, Terry, and Bene.

10. Applicant's new claims are rejected in view of various combinations of Lynch, Terry, Bene, and Wong.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
22 July 2008